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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,471

04/03/2006

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,471	Applicant(s) NAKANO ET AL.	
	Examiner Maureen M. Wallenhorst	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/3/06, 11/29/06</u> | 6) <input type="checkbox"/> Other: ____. |

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1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).
4. Claims 6-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 6 of copending Application No. 10/576,268. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because both sets of claims recite a method for treating uterine cervix cells comprising the step of removing mucus from the cells by combining the cells with a cysteine and/or a compound derived therefrom.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Castegini et al (WO 00/59500).

Castegini et al teach of a composition having a high content of N-acetylcysteine as a mucolytic agent to break-up and remove mucus from a specimen. The composition comprises 80-95% by weight N-acetylcysteine. See the abstract and pages 1-2 of Castegini et al. Since instant claims 1-2 recite a composition comprising cysteine or a compound related thereto in an amount of 5 mass% or more, the composition disclosed in Castegini et al containing 80-95% by weight N-acetylcysteine anticipates claims 1-2. A statement of intended use in the preamble of a composition claim does not render the composition patentable over an otherwise old or suggested composition. See *In re Pearson*, 181 USPQ 641 (CCPA 1974).

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Motono (US 4,946,472).

Motono teaches of a composition comprising 5.0% by weight of L-cysteine in a solvent of pure water. See lines 35-45 in column 6 of Motono. Since instant claims 1-4 recite a composition comprising cysteine or a compound related thereto in an amount of 5 mass% or more in combination with a solvent such as water, the composition disclosed in Motono containing 5% by weight L-cysteine anticipates claims 1-4. A statement of intended use in the preamble of a composition claim does not render the composition patentable over an otherwise old or suggested composition. See *In re Pearson*, 181 USPQ 641 (CCPA 1974).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 63168562 (submitted in the Information Disclosure Statement filed on April 3, 2006).

JP 63168562 teaches of a cell preserving liquid that comprises ethyl alcohol in an amount of 30-40 mass%, a phosphate buffer solution and methyl cysteine as a mucus dissolving agent. See the English language abstract of JP 63168562. JP 63168562 fails to teach that the amount of

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methyl cysteine in the cell preserving composition is 5 mass% or more. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to vary the concentration level of the methyl cysteine in the composition taught by JP 63168562 to 5 mass% or more in order to fully remove all mucus from mucus-producing cells at the same time as not damaging the cells, and where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover optimum values for a known result effective parameter such as concentration level of a component in a composition. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

11. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al (WO 03/020986).

Katz et al teach of a method for isolating and treating cells. The method comprises the steps of obtaining a sample of cervical mucus cells (i.e. uterine cervix cells), treating the cells with a mucolytic agent such as N-acetyl-L-cysteine and enzymes such as collagenase and protease, separating the treated cells by centrifugation and washing the separated cells. See pages 3 and 8-10 of Katz et al. Katz et al fail to teach that the amount of N-acetyl-L-cysteine is 5 mass% or more. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to vary the concentration level of N-acetyl-L-cysteine in the composition and method taught by Katz et al to 5 mass% or more in order to fully remove all mucus from uterine cervix cells at the same time as not damaging the cells, and where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover optimum values for a known result effective parameter such as concentration level of a component in a composition. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

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12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Pollard et al who teach of a process of mucolysis; and White who teaches of a process for the liquefaction of mucus.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

February 8, 2008

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797